Four decades of Health Advocacy for Rational Drug Policy and Rational Drug Use

Limited statement on baseless allegations of collusion with the Indian pharmaceutical industry

All India Drug Action Network (AIDAN)

2 May 2023

We have been made aware of a baseless and absurd allegation made by Mr. Dinesh Thakur on 29 March on social media that "…public health activists in AIDAN are in bed with pharmaceutical industry" (https://twitter.com/d_s_thakur/status/1641056277936709640?s=20). Mr. Thakur and his colleague have previously made disparaging statements along the same lines about AIDAN in their book, the Truth Pill, which we strongly feel are unjustified, uncalled for and in bad taste. Through this brief statement, AIDAN would like to put in public domain, a summary of our work over the last four decades so that the absurdity of this allegation becomes evident.

Mr. Thakur through some tweets has also indulged in malicious, misleading allegations against LOCOST, a member of AIDAN. Theses have been properly responded to by LOCOST in its statement of 2 May 2023 (available at https://tinyurl.com/yckh3dcb).

Working on a range of regulatory concerns to achieve a people oriented, rational drug policy

AIDAN and its members have been committed health advocates for a Rational Drug Policy and for the Rational Use of Drugs since the 1980s, promoting the rational use of medicines and addressing safety and quality concerns in the promotion, sale and use of medicines. AIDAN recognizes that access to essential medicines and medical products is a major aspect of Comprehensive Primary Health Care, the Alma-Ata Declaration of 1978, and the idea of Universal Health Care addressing social determinants of health.

It is difficult to capture the breadth of AIDAN's work since it was founded in 1982. Our work has spanned a wide range of areas in pharmaceuticals and drug regulation; promoting rational use of medicines; pushing to revamp regulatory mechanisms with the aim of weeding out irrational medicines and irrational fixed dose combinations (FDCs); advocating for effective drug price regulations; expansion of the National List of Essential Medicines List (NLEM); strengthening and reviving public sector production of medicines and public pooled procurement of medicines; price regulation of medical devices such as cardiac stents; advocating for better patient safeguards in medical device regulations and accountability for harmful medical devices (like the faulty Johnson & Johnson hip implants); transparency in clinical trials; use of TRIPS-flexibilities to improve access to medicines; advocating to replace the Uniform Code of Pharmaceutical Marketing Practices (UCPMP) with legal provisions to regulate the marketing and promotion of medicines and medical devices; and more.

AIDAN during the COVID-19 pandemic

During the COVID-19 pandemic, we worked intensely in many areas and engaged with government policies. We consistently advocated for greater transparency and public sharing of data & information by the Government in relation to regulatory approvals of COVID-19-related medical products (tests, vaccines, therapeutics, PPE), procurement, protocols etc. In monitoring the development of various vaccines and therapies for use in COVID-19, we have exposed irregularities in some clinical trials of vaccines and drugs; raised concerns regarding the grant of emergency authorisation without adequate data/scientific basis for some products; and concerns over the lack of transparency of the collaborations/partnerships of local vaccine manufacturers with government research institutions and public sector manufacturing units. As the national vaccine rollout took off, we advocated for free vaccination as a public health measure and to ensure equitable access to vaccines. We also flagged concerns with authorities about early cases of severe, rare adverse events following immunization (AEFI) and advocated for greater public awareness of AEFI, for making AEFI reporting mechanisms accessible to the public, for strengthening investigations of AEFI and transparency in causality assessments by the expert committees involved, and the provision of medical management and compensation to vaccine beneficiaries suffering adverse events. We also worked on several other aspects including the regulation of private hospital treatment charges by state governments; price regulation of life-saving medical devices; consumer fraud by diagnostic labs and e-healthcare platforms offering COVID-19 testing; and provided support to families in distress due to inflated medical bills and overcharging by private hospitals.

Promoting patients' rights

Our work on broader aspects of access to healthcare such as demands for regulation of private sector healthcare institutions including billing charges, promotion of patients' rights and grievance redressal mechanisms, advocacy for greater regulation of diagnostic labs, etc., has been informed by our direct involvement in supporting individual patients/consumers and their families.

One of the first drugs that women's groups and consumer groups were deeply concerned about were high-dose estrogen progresterone fixed-dose combinations (FDCs) which were rampantly being promoted, sold and prescribed for indications that did not exist in medical textbooks and without warnings about potential teratogenic effects (birth defects). Founding members of AIDAN were involved in the campaign for banning of these drugs through the 1980s.

Over the years, AIDAN and its members have been involved in several landmark public interest litigations (PILs). Recognizing the enormous economic waste and health harms arising from the purchase of costly medicines many of which were clearly irrational and potentially hazardous, Drug Action Forum-Karnataka (DAF-K), AIDAN and National Campaign Committee for Drug Policy (NCCDP) filed a PIL (693/1993) in the Supreme Court to screen and weed out irrational and hazardous medicines in the Indian market. As a consequence of this case, several categories of irrational medicines were weeded out (chloramphenicol streptomycin FDCs that were being sold for childhood diarrhoeas, streptomycin penicillin FDCs that were being widely sold for fevers and infections without warning about the need for penicillin sensitivity testing and

potential for creating drug resistance in TB treatment; cough syrups containing both cough suppressants and cough expectorants etc.) and the formulation for oral rehydration salts (ORS) was standardised.

AIDAN has also been involved in PILs related to, inter alia, challenging the government's proposal to reduce the list of drugs under price control (Pharmaceutical Policy 2002) and subsequently challenging the market-based drug pricing policy of the DPCO 2013; accountability for HPV vaccine-related deaths, banning of irrational drugs and FDCs (e.g., irrational topical FDCs containing corticosteroids, cough syrups containing codeine that were banned as part of the initiative of the government to ban more than 300 irrational FDCs); transparency of rotavirus vaccine clinical trial data; opposing the government's attempt to restrict the manufacture, sale and distribution of oxytocin that could threaten access to this life-saving medicine; expanding regulation and ensuring enforcement of COVID-19 hospital treatment charges, and improving public health responses to the COVID-19 pandemic in Maharashtra and Delhi.

In recent years some of our most challenging work has involved supporting patients in their quest for justice, whether it be the victims of faulty Johnson & Johnson metal-on-metal hip implants, families of COVID-19 patients who were victims of exploitation in private hospitals or supporting organisations working with the victims of ethical violations that took place in the clinical trial of a COVID-19 vaccine in Bhopal.

Driven by public interest

AIDAN's work has always been driven by public interest in all of our contributions, and our positions are often critical of or at loggerheads with industry, trade or the government. But we have also been supportive of governmental policies in some instances (e.g., the banning of irrational medicines and irrational FDCs, regulating prices of medical devices like coronary stents and knee implants, price control of anti-diabetic and cardiovascular non-scheduled formulations through the DPCO 2013).

We work as a collective and members of AIDAN are well-regarded experts and resource persons on a range of issues related to medicines, diagnostics and medical devices.

We believe our work speaks for itself and is well recognised among stakeholders and government. We remain committed to increasing access to and improving the rational use of essential medical products and services, advocating for a rational drug policy and working on the many public health challenges before all of us.

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